

**Testing All U.S. Cows for BSE Not Necessary, Officials Say
In Japan, they say beef trade should be science-based**

U.S. officials visiting Japan said the United States does not think it is necessary to test for bovine spongiform encephalopathy (BSE) in all slaughtered cattle to ensure the safety of U.S.-produced beef.

In a January 23 press briefing in Tokyo following a meeting with Japanese officials, J.B. Penn, U.S. under secretary of agriculture for farm and foreign agricultural services, said it is neither efficient nor effective to do "massive testing" of younger cattle in which BSE "is very unlikely to manifest itself."

Japan, which experienced BSE --- or mad cow disease -- in 2001, tests 100 percent of the cattle it slaughters. The country has banned the import of beef from the United States since a single case of BSE was found in December in Washington state.

The United States concentrates its testing on "higher risk" animals, including older cows and cows that have calved, because the system provides the highest probability of identifying animals that would exhibit the disease, said Charles Lambert, deputy under secretary of agriculture for marketing and regulatory programs. This is the same testing system used in Europe and other countries, he said.

Penn said that while both Japan and the United States have agreed they want a resumption of U.S. beef trade "as quickly as possible," the United States wants the resumption to be based on "solid science" principles that give "maximum reassurance of consumer safety."

Penn described the meeting as a "meaningful" and "productive" exchange of views and information. A follow-up meeting is planned for February, he said.

He said that because there is a "great need" to reassure Japanese consumers about the safety of U.S. beef, the U.S. officials repeatedly stressed that beef from the United States is safe.

Lambert said the United States federal government is "moving forward very aggressively" --- including coordinating with state governments and the beef industry --- to develop a national identification and tracking system for cattle.

Japan initially sent a delegation to Washington, D.C., and Washington state days after the case was announced December 23 to gather information about the country's first-ever case of BSE.

In 2002, the last year for which statistics are available, the United States exported \$1 billion worth of beef to Japan, or nearly one-third of its total beef exports, Penn said. About nine percent of total U.S. beef production is exported, he said.

U.S. beef accounts for 29 percent of beef consumption in Japan, Penn said. It is unlikely that other country suppliers, such as Australia, would be able to totally meet Japan's demand for beef, he added.

Following is the transcript of the press briefing:

U.S. Embassy-Tokyo Press Office
TRANSCRIPT

Dr. J.B. Penn, Under Secretary of Agriculture for Farm and Foreign Agriculture Services
Dr. Merle D. Pierson, Deputy Under Secretary of Agriculture for Food Safety
Dr. Charles Lambert, Deputy Under Secretary of Agriculture for Marketing and Regulatory Programs
Mr. David Hegwood, Special Counsel to the Secretary of Agriculture
Dr. Lester M. Crawford, Deputy Commissioner, Food and Drug Administration [FDA]

Press Conference
January 23, 2004
U.S. Embassy Auditorium
Tokyo, Japan

MODERATOR: Good evening everyone. I am Michael Boyle, the Embassy spokesperson. I would like to say a couple of words before we begin. First, thank you for being here, thank you for waiting patiently. We are on the record tonight. We will have simultaneous translation, which means that when you ask a question, please use the microphone so that the translators who are in the booth up above can hear. We ask you, when you ask a question, to ask one question at a time. Please identify yourself, your organization, your name. And without further adieu, let me introduce Dr. J.B. Penn, Under Secretary of Agriculture, who will introduce the rest of the group.

PENN: Thank you very much. With me today are colleagues David Hegwood, Special Counsel to Secretary Veneman [Agriculture Secretary Ann Veneman]; Dr. Chuck Lambert, who is Deputy Under Secretary for Marketing and Regulatory Programs at USDA [U.S. Department of Agriculture]; Dr. Merle Pierson, who is the Deputy Under Secretary for Food Safety; and Dr. Lester Crawford, who is the Deputy Commissioner of the Food and Drug Administration. Now these folks have the responsibilities for the regulation of animal feed in the U.S., food safety, animal health, trade. So most aspects that relate to BSE are represented on the platform today. We have just concluded an afternoon-long meeting with our colleagues from the Japanese Government, the Ministry of Foreign Affairs, Ministry of Agriculture, Ministry of Health, Labor and Welfare. So all of those folks.

This meeting today was a follow-up to on-going discussions that we have had with the Japanese Government since the announcement of this confirmed case of BSE in the U.S. on December 23rd. Shortly after, within a week after that announcement, both David Hegwood and Dr. Lambert came here. We began the process at that point in time of sharing information, of keeping our trading partners informed as to our investigation and as to subsequent actions.

Just a week ago, the Japanese government had a delegation of technical specialists to the U.S. They came to Washington, D.C., they went to Washington state, they got a first hand view of what we were doing with the investigations of the new measures that we announced on December 30th to further strengthen our food safety system. Secretary Veneman and Minister [Yoshiyuki] Kamei from the Agriculture Ministry have been in contact by telephone. In fact, this trip and this meeting are a direct outgrowth of a conversation they had just about a week ago, at which time they agreed that it was time to move the discussions to a policy level and that's the reason that we are here.

The two ministers agreed that they have a common goal of resuming trade as soon as is practical. We want to resume trade as soon as possible based on continued use of solid science, scientific principles for developing the regulations. And we want to assure consumers, both in Japan and consumers in the United States, that we continue to have a very safe and highly effective food regulatory system, and we certainly want to assure Japanese consumers of the safety of U.S. beef.

This is a very important market to the U.S. livestock and meat industry, as we have repeatedly said. This market accounted last year for about one-third of all of our exports, and it's a market in which our industry has had a big hand in helping develop over two decades, so it's very important to us that we try to resume trade as quickly as possible and avoid any erosion.

In the meeting today we had a very good exchange of information, as I said we spent several hours in very intense discussions. Both sides presented information to the other side, posed detailed questions, requested elaborations; it was a thorough going exchange of information. The Japanese side presented the report of the investigation of their technical team, which had just been in the U.S., as I indicated, and we had some questions and requested some clarifications about that. And our side explained the new measures that we have taken to further strengthen and enhance our food safety system and to assure consumers domestically and internationally of the safety of the food system.

There were no new proposals presented from either side and, overall, I would characterize the meeting as the usual words -- meaningful, productive. It was a very necessary exchange of views in what I consider an on-going process that we hope will lead to a conclusion of a resumption of trade. We agreed to a subsequent meeting next month, with a specific date not set. We will exchange information in the meantime. With that, I would stop and we will invite your questions and we have, as I said, people who are very knowledgeable in various areas and so we will try to respond as we can. So we'd be happy to respond to your questions.

QUESTION: (Toshio Aritake, Bureau of National Affairs) Have you discussed the possibility of introducing a new safety measure which Japan is demanding? Japan is requesting 100 percent testing. If Japan picks up, foots that cost of inspection fully for cattle to be exported to Japan, is it something the U.S. side can accept?

PENN: Well, as I indicated, we want to see the resumption of trade as quickly as possible, but there are certain conditions that we want to see go along with the resumption of that trade. As I said before, basing the trade on solid science, scientific principles, is very important to us. Doing it in a way that gives maximum reassurance of consumer safety is also a way that is very important to us. But we did discuss the possibility of 100 percent testing, and we have reviewed the scientific basis for that and, for the purposes for which we have a surveillance system we think it not necessary to do 100 percent testing. As we have all discussed over and over, this animal disease manifests itself in older animals, not in younger animals. We think that it is not an efficient use, effective use of resources to do massive testing in younger animals where the disease is very unlikely to manifest itself. We think those resources should be devoted to the higher risk population, so we have a different philosophy, a different approach to testing than the Japanese. And it is a matter of trying to base this on science, regardless of the cost, who might have to pay the bill.

Q: (Peggy Hernandez, Boston Globe) I just had several questions regarding the Japanese trade. You said that Japan imports one third of its beef, or that the U.S. exports one-third of its beef exports to Japan. I wonder if you can estimate the cost of that trade to Japan, the size of the export, and calculate the loss to the American livestock industry.

PENN: I can take a stab at that then I'd invite my colleagues to elaborate. As I said, in 2002, the most recent year for which we have complete numbers, the U.S. total exports were \$3.2 billion of beef and beef products, and of that the Japanese market accounted for one billion dollars, or just about one-third of the total. Now the U.S. exports about nine percent of its total beef production. And the remainder, 91 percent, goes entirely to the domestic market. So the loss of almost 10 percent of the market for your product is a very considerable one, and we have seen the economic response to that in the U.S. already. Cattle prices have declined since the announcement of this incident by about 15 percent. We had near record cattle prices before the announcement and so they have fallen, but they are still above where they were a year or so ago but, nonetheless, it is a very adverse economic consequence to the domestic cattle producers.

Elsewhere throughout the system you begin to see economic effects as well, the meat packing facilities don't run as long hours as before and they reduce the shifts and potentially will have to lay off workers. So there is an economic consequence throughout the U.S. system.

Now turning to the other side, U.S. beef accounts for 29 percent of the Japanese beef consumption in the most recent year. That is a very substantial part of the protein in the diet of Japanese consumers. And as the supply of U.S. beef is no longer available, other suppliers, of course, will try to meet that demand. It is highly unlikely, in the current market conditions, that other suppliers, Australia and others, would be able to do that. So one could expect that prices will begin to rise, that the product will not be available, and in certain restaurants, certain uses, the product will not be available. And if the ban resumes for a prolonged period then consumers will shift their purchasing patterns and will probably begin to purchase other products, which is a result that we would not like to see. That is why we would like to see the ban lifted as soon as we possibly can.

Q: (Kyoko Morisawa, NTV) The employee of (inaudible) Lake Meat said that infected cow wasn't a cow "downer," the cow was a walker. If that is true, Secretary Veneman had a false statement and obviously the ban on downer cows is not enough, what do you think about it?

PENN: I'm going to ask Dr. Pierson, the Food Safety person, to respond and then Dr. Lambert.

PIERSON: I saw the report on the animal in question, and the animal was examined by our inspectors prior to going through the plant and was one of a group that day tested for BSE. It was identified as an animal possibly of a little bit higher risk because it calved and it demonstrated partial paralysis, and that is why it was identified as a result, again, of the calving. And so it was identified, it was in fact tested and the result was that the test came back positive.

LAMBERT: The testing regime that we use involves testing what we consider the high-risk population, and that includes animals that were in this category, the non-ambulatory animals, so we do feel that by testing this high-risk category that it provides the highest probability of finding animals that would exhibit the disease. That's been shown in Europe and in other countries, and that the highest probability and most cost-effective manner of use of resources is in testing that population.

Q: (Taro Kurosaki, Herald Asahi) I would just like to confirm a portion of the answer to your first question. Was there any proposal from Tokyo to shoulder the burden or cost of testing all cows and, related to that, I would like to know if there were any proposals for alternatives to testing all cows, from Japan and if you made any proposals.

PENN: The answer is "no" and "no." We, as I said, we did talk about 100 percent testing, but we were talking about the relative merits of that system versus other systems and we didn't discuss, we did not discuss, who might bear the cost of such a system. As I said in the opening statement no proposals were advanced from either side.

Q: (Kenji Hall, Associated Press) There's a sense that, because the United States lacks a nation-wide standardized electronic ID and tracking system, the investigation was slowed to an extent. Has the Japanese side indicated that this is something they would like to see put into place and, specifically, does the U.S. have any plans at this point to put that into place?

LAMBERT: Yes, the USDA has been working with representatives of state governments and representatives of the various industry organizations for about the last 18 months to develop an animal identification program, and the find of this animal in Washington state, this case of BSE, has accelerated the implementation of this program. We are still working out some of the details, but we are moving forward very aggressively putting resources towards premises ID, some pilot projects, and putting together the infrastructure so that this animal ID system will be up and running. That system has not been a primary topic of conversation, I would say, with the

Japanese government, but that's an underlying, I think, measure that we have taken and that all of our trading partners have indicated we need to move toward.

PENN: And this was one of the half dozen or so initiatives that were announced on December 30th -- the accelerated development of this animal ID system that he just described.

Q: (Miho Yoshikawa, Reuters) Am I correct in understanding that what happened today was mostly an exchange of information, and the actual topic of resumption of trade itself was not discussed during your talks with the Japanese officials?

PENN: Well, no, I wouldn't say that. The main content of our discussion today was about the resumption of trade, but it was about the conditions that would be necessary for trade to resume. We were presenting our information to reassure the Japanese government officials and reassure Japanese consumers that the steps that we have since the find of this one Canadian cow in Washington state have further strengthened what was an already robust system. So we were presenting information in that regard, and then the Japanese side was presenting the information that their technical experts had gathered and assimilated, and we were providing clarifications where possible.

Q: (Hayato Ishii, Kyodo) Apart from the government-to-government level meeting you had today, are you planning to meet others, like Parliamentarians and so forth of Japanese National Diet? If you have done so, what is the general impression that you have gained from Japanese today? Any general interpretation about the Japanese reaction.

PENN: I'll ask my colleagues to elaborate. We have had several meetings with various parties, stakeholders if you will, in the issue before us and we've developed -- certainly I have developed - several impressions. One of the first impressions I got is that, given the particular circumstances in the Japanese market, that there is a great need here to reassure Japanese consumers about the safety of the food supply -- certainly the safety of the US beef supply. And that's one of the things, one of the messages we've been trying to stress over and over is that our beef is safe, is that our system is very good, that we have, yes, discovered one Canadian origin cow in Washington state, but the system worked. We found the cow and we have now further strengthened that system. So that's one impression I have. The second impression is that there's an enormous sense of good will here, that this is not a situation in which there is hostility, but there is a genuine desire for cooperation and to return to normal as quickly as is practical. I just took a great amount of time to describe the economic consequences on both sides. We met with a lot of people here who have a lot at stake financially and are trying to get the system resumed. It affects employment, it affects economic activity, so there are a lot of people with a lot of good will and we certainly found that among the government officials, that there is a very cooperative spirit, a cooperative attitude to try to work through this issue. Those are a couple of my impressions. I'll ask my colleagues if they'd like to say something.

Q: (Koichi Yamamoto, Asahi Shimbun) I was wondering about the possibility of exploring a system of BEV program -- Beef Export Verification program. Is there a possibility to introduce some testing system into the program? That's one question, and the other is I understand that you have requested to lift the ban for pipeline products, beef box, as a top priority for the Japanese market. Have you discussed this during this conference? Thank you.

HEGWOOD: Well, I'll respond to the part about the BEV system. That was a system put in place back in July, resulted from discussion in July after the find of positive BSE cow in Canada. Essentially what that program does is ensures that all meat products coming from the U.S. do not contain any Canadian-origin beef. So it's not sure if that system would have to remain in place if we were to be able to resume trade. Certainly we would be willing to explore ways to provide science-based assurances through some type of certification program, but we didn't get that far today. As Dr. Penn said, we were talking about the measures that we put in place. So we didn't

get as far as talking about the actual implementation of whatever conditions we would ultimately agree to.

PENN: The second part of your question related to the pipeline beef supplies. There is some considerable amount of beef that is here, that arrived and has not been admitted by the customs officials. We have had discussions about the disposition of that product in the United States. We have had discussions here with some of the importers, the exporters, the people who own the product. A lot of that is subject to commercial contract -- standard commercial contract -- and is as yet not exactly an issue for the two governments. We did not discuss the pipeline issue in our meeting this afternoon.

Q: (Leika Kihara, Dow Jones) You said there were no new proposals made from either Japan or the U.S. side, and you also said that there would be a meeting later on. Is there any possibility each side would make any new proposals, considering that there seems to be a gap between the opinions of both sides on this issue. And if there is any date—since you want to resume trade as soon as possible -- is there a date you want to meet, a specific date the US wants to meet with Japan?

PENN: Well, thank you for the questions. I characterized the meeting today as part of a process. This is a process, because this was an extraordinary event -- the finding of this one BSE infected animal -- and now we have to work through the process. That involves sharing information, taking extraordinary measures to improve the system in our country, to try to harmonize that with the Canadian system to the extent that we can. And the meeting today was another necessary part of the process. We have to share information and understand the requirements of the Japanese side. We wanted them to better understand the steps we'd taken, and see how close that we could come together, and we did that. It was successful in that regard and we have agreed to meet next month. We didn't set a specific date, but I would think that as soon as is practical. We have this international review team, as you know, that was established by Secretary Veneman to review our system, to review the new actions that we have taken. That team is meeting in Washington this week and we would expect it to issue its preliminary report in a few days time. I would expect that we would like to review the preliminary report before our next meeting, so I think our next meeting could take place sometime soon thereafter. At that time, I think we are moving toward the development of specific proposals, or specific ideas or specific reassurances, steps that would be necessary to get the trade resumed. And from our point of view, as I said, we'd like to see that resumed as soon as possible. I know from the Japanese business community side, they'd like to see it resumed as soon as possible, as well.

Q: (Kuniko Ishihara, Nihon Nogyo Shimibun) I have two questions. First, Secretary Veneman had announced on the 30th of December the additional measures -- what has been the progress made so far? Have you implemented fully all the measures announced then? And there are 23-month old or 21-month old cows which the Japanese government would like to see being inspected, but US has not recognized such a request from Japan—testing those young cows, 23-month old, 21-month old?

PENN: OK. I will ask Dr. Pierson first to respond to the measures, because I think that most of those occurred in his area.

PIERSON: On December 30th, Secretary Veneman announced we would no longer allow downer cattle to be processed and to go into the food supply. That was effective immediately upon that announcement. On January 12th, we issued three regulations and a rule. One of these related to the holding and testing, or to hold any animal that was tested for BSE, and not allowed for release until such time as the test results were back, and only a negative animal -- negative by test -- would that animal be allowed for processing for food. Another rule related to the Specified Risk Materials, in which we identified Specified Risk Materials based upon international criteria and the best available science, and the rule on Specified Risk Materials took affect on January 12th -- the same day they were issued. Another rule related to Advanced Meat Recovery, and this Advanced

Meat Recovery process is one by which we will do additional testing on, and that also became effective on January 12th. So all those measures that Secretary Veneman announced were either immediately placed into effect or all were placed into effect upon our issuance of the rules.

PENN: OK, the second part of your question I wasn't quite sure I understood it, but I'm going to ask Dr. Lambert to respond and if he didn't quite understand it, you can ask again.

LAMBERT: As I understand it, the question was regarding the 21- and 23-month old cattle that have been found in Japan. I think it is important to understand that two of the three tests that the Japanese government conducted on those animals were negative. And so there is some question in the international scientific community about whether those were test aberrations or just what those results were. The slides have been submitted to an OIE (World Organization for Animal Health) lab in England and the negative results were confirmed, as we understand it. So, again, we have continued to focus on the high-risk population that results in findings in the EU and other countries where they have had high incidences of BSE have tended to be in older animal populations and in the higher risk populations. And that is where we have continued to focus our surveillance efforts to continue to identify if we have that problem in our population and to what extent.

Q: (Peggy Hernandez-Boston Globe) I'm just trying to get a sense of the urgency here. You know, you've mentioned several times that there is a loss to the Japanese businesses, the American businesses; is there any kind of calculation on what we're looking at on a daily basis, a weekly basis, or a monthly basis, or some measure that our readers can understand? You also said there is beef in the Japanese pipeline; I'm wondering how much that is? Is there a goal to when you hope trade will resume? Are you looking at this summer? Is this ban going to go on until the summer? That's a lot of money! That's a lot of jobs, too, in both countries and I'm just trying to get a sense of the human reality of this ban.

PENN: Well, I took a long time a moment ago in response to your first question and apparently I didn't do too good a job. I was trying to indicate that, yes, you're right, this is an economic disruption, it's an economic dislocation. The normal economic activities have been altered. Now, from the U.S. side, again, there is a loss to the U.S. cattle producers, there is a loss to the packing industry, to the transporters, and there will be some loss of jobs as a result of this. I mean, we suddenly have had over three billion dollars worth of exports abruptly terminated for the most part. Here, the same sort of thing -- again, people who normally deal in imported product, people who work in the restaurants, people who are involved in the food-service industry... yes, there is an economic dislocation. And it is, again, in everyone's best economic interest to try to get trade resumed as quickly as possible, but there are other considerations. And those considerations are reassuring the Japanese consuming public that the U.S. has done all of the things that are appropriate to do to make sure that the beef supply is safe, and that is what we're trying to do. That's why this is a process that does take some time, but I can assure you that we want to do it, but we want to do it in the right way. We don't want to just rush into this, we want to make sure that we're doing everything first and foremost to protect consumers. The public health is the paramount consideration.

Q: (Kenji Hall-Associated Press) Was there any sense that the steps the U.S. has taken so far are any closer to what Japan needs to see before it lifts the import ban? And was there any indication in your talks today that Japan might relax its demand for 100 percent testing? Or is it asking for the U.S. to do more? Thank you.

PENN: Well, I repeat again, part of what we were doing is getting to the answers to those questions, where we were trying to share information as to what we had done. The Japanese technical team was in the United States, it was learning more about our measures. It was learning more about our investigation of this one animal. And the Japanese officials are now evaluating and assimilating all of that information, plus, I would hope, the new information that we were presenting today. At the same time, the Japanese have called for 100 percent testing. They have

indicated some other requirements. So while they are evaluating our position, we're going to be going away and evaluating their position. And, as I have already explained, we have agreed to meet again next month to see if we can begin to come together.

Q: (Kyoko Morisawa, Nippon TV) In the Moses Lake, according to the meat packers there, with regard to SRM, when the meat is being processed, first of all, the beef will be cut into half and the risk material will be removed. Which means the powder or the blood might be splattered on the meat which will be edible or eaten by human beings, so I was wondering how perfect or how effective the ongoing tests will be? So tests might not be adequate, that is why maybe all cattle need to be inspected and so forth. And sampling test is also being conducted, but maybe the sampling tests have not been conducted as they should have been? So, any observations on this point?

PENN: We do have some observations. I'm going to ask Dr. Pierson to begin.

PIERSON: OK, thank you. Our rules that took effect on January 12, to address Specified Risk Materials, requires the processor to develop, implement and maintain plans for the removal of Specified Risk Materials, and for the control or disposition or disposal of those materials, and the control of the materials during the processing operation. We have, at our meat processing companies, an inspector present all the time that the animals are being slaughtered and going through the process. Our law requires what you call continuous inspection -- every animal is inspected by a government inspector. And the company must meet these regulatory requirements for the removal of Specified Risk Materials. Our inspectors have been provided with directions on what to do in case there should be cross-contamination and the actions to take. We're confident that what has been implemented is effective and the Specified Risk Materials are effectively removed.

PENN: OK, I've noticed a pattern, all the questions seem to come from right here in the front. Are there any questions way in the back? OK, here is one in the back. Then you, OK.

Q: (Tim Kelly, Bloomberg News) I just want to clarify the next stage in the process. Today was a meeting to exchange information. At the next meeting, next month, will you be coming to the table with specific proposals, and do you expect the Japanese side to come to the table with their own proposals that you will hammer out and discuss to try and reach an agreement? Will the next meeting be in Tokyo? And will it be the same members from the U.S. side?

PENN: Well, the one thing that I can tell you for sure is that we agreed to meet next month, and I have before described this as a process, and this was information exchange today. I think, as you move down the process, that you do have to get to more specifics. You do have to get more concrete ideas that can be discussed, and I would expect the next meeting to be one where we're discussing more specific, more concrete steps that would lead to the resumption of trade. I would expect that some of the same people would be involved, certainly from our side, in the next meeting. I would assume so for the Japanese side.

Q: (Mitsuru Obe, Jiji News Agency) You have talked so much about 100 percent testing, so I have a question about the 1997 law banning the use of bone meal from ruminants and your claim of 99 percent compliance. As far as I know, that claim was actually challenged by the General Accounting Office (GAO) in 2002. And also there has been a suggestion that this 99 percent figure isn't so much of a comfort to consumers because the actual figure doesn't include, doesn't cover small farmers. So what do you say about these charges?

PENN: Thank you very much for that question. We have noted that there is quite a lot of misinformation around, and I am happy to say that Dr. Crawford can set the record straight, I would hope once and for all.

CRAWFORD: It's my pleasure. First of all, the 99 percent compliance rate is correct. That's as a result of audits, of inspections and tracking actually when inspectors go to a farm. And so we have virtual complete compliance with this particular regulation, the meat and bone meal ban or the so-called animal feed ban in the United States. Actually, the compliance rate for that is the highest of any FDA compliance program in all of the categories of products that we regulate. It is probably the most effective regulatory program that FDA has had in its 100-year history.

The GAO report that you mentioned was published in 2002 and it talked about their earlier years, 1997 to 2000 where, as we began the program and we expanded it to include all 13,000 feed-producing facilities in the United States, both large and small. There was a start-up problem, so that we didn't have the compliance in the early days that we do now. However, the compliance problems that were highlighted in that report related not to meat and bone meal getting into animal feed, but technical irregularities. The majority of these technical irregularities were, in fact, the lack of records and the lack of record keeping.

A regulation like this does cause dislocations in the way business is conducted in a given industry. In that particular case, anyone producing animal feed and anyone buying animal feed had to keep a record where they got it from, what the ingredients were, and so forth. Now let me address the problem, finally, of whether or not small facilities are involved. Even if a person in the United States buys only one bag of feed a year to feed half a cow, they still have to be in complete compliance with this particular regulation. The fines for non-compliance are extraordinary. If you violate the animal feed regulation of the United States, you may be fined up to two million dollars for each violation or two million dollars per day as long as you are out of compliance. You also may face a jail term of five years for each violation. Nobody wants that. And FDA is convinced there are no lapses in this.

The other thing that was brought up was perhaps animal feed could be brought in from Mexico, or from Costa Rica or Canada or wherever, and it would escape FDA's attention. The regulation is clear—no one can bring it in from anywhere. With the passage of the Bioterrorism Act in the United States in 2002, we've got a lot more strength with that. You may not bring any kind of product that is regulated by FDA into the United States without notifying us that it is coming, keeping records and allowing inspection and detention of the product. We have a very efficacious animal feed ban and the record is clear — anyone can investigate and see what it is. It's also been in place for seven years. We have the same kind of experience that few countries have in terms of keeping animal feed supply safe.

MODERATOR: OK, are there any more questions? One in the back.

Q: (Taro Kurasaki, Herald Asahi) This is a basic question. Were there any, in the discussions, was there any information from the Japanese side that you noticed was perhaps based on misperceptions, and did you have to correct that?

PENN: Well, I don't know that I would characterize information as being misperceptions. We did have full and frank discussions. We had a lot of detailed discussions. A lot of our discussion focused on explaining and describing our system, comparing and contrasting it to the Japanese system. There was a lot of detailed discussion, but I think it was largely to educate and inform and to explain, as Dr. Crawford just did, about some perceptions that have emerged. OK, one more.

MODERATOR: Let's make this the last question. We have gone on now for some time.

Q: (Miho Yoshikawa, Reuters) I've heard the U.S. maintains a ban on imports of Japanese beef into your country. I was just curious as to the reason for this ban being maintained.

PENN: We do have a ban on beef from Japan and it's because of the outbreak of BSE that occurred in Japan. The ban continues because no one has asked that it be lifted. That's the first

step in the process. I don't mean to be flip about that, but we do have a process whereby we would go through a risk assessment, a detailed evaluation of what transpired in a country that has had an outbreak of BSE. Just much like we're going through at the present time. What were the circumstances surrounding the outbreak, what were the sources, what happened to the animals and then what ameliorations measures have been taken? What steps have been put in place, both to prevent the spread of BSE in the animal population and what preventive measures have been put in place to protect the public health? So we would go through an evaluation of that kind for any country that has an outbreak of BSE and then asks to have trade resumed.

MODERATOR: Thank you very much.